

SM.



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/028,482	12/21/2001	Janet A. Warrington	3445	2372

22886 7590 03/10/2004

AFFYMETRIX, INC
ATTN: CHIEF IP COUNSEL, LEGAL DEPT.
3380 CENTRAL EXPRESSWAY
SANTA CLARA, CA 95051

EXAMINER

SMITH, CAROLYN L

ART UNIT PAPER NUMBER

1631

DATE MAILED: 03/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SA.

Office Action Summary	Application No. 10/028,482	Applicant(s) WARRINGTON ET AL.	
	Examiner Carolyn L Smith	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 15-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 15-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10272003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' elections without traverse of Group I (claims 1-7), species B (sample which is from a diploid organism) and sub-specie (model A-C), filed 1/5/04, are acknowledged.

Cancelled claims 5-14 and new claims 15-27 are acknowledged. The specie and subspecie election requirements have been withdrawn so that examination is extended to include all species and subspecies within the elected restriction group of claims.

The information disclosure statement, filed 10/27/03, has been fully considered.

Claims herein under examination are 1-4 and 15-27.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, such as on page 11 (line 17), 12 (line 11), 16 (line 8), 32 (line 6), and 40 (line 9). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claims Rejected Under 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1631

LACK OF WRITTEN DESCRIPTION

Claims 16 and 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants point to support in the specification for claim 16 on page 40, lines 4-5. While support is provided for two laboratory personnel to sample, hybridize, and analyze 40 arrays per day, there does not appear to be support for the phrase “at least 35 kilobases of sequence”, as stated in claim 16. Applicants point to support in the specification for claim 22 on page 30, lines 10-15. While support is provided for simultaneous screening of 30 kb of sense and 30 kb of antisense DNA, it does not support the phrase “at least 30 kilobases” as stated twice in claim 22. Because the introduction of “at least 35 kilobases of sequence” (claim 16) and “at least 30 kilobases” (claim 22), filed 1/5/04, does not appear to have support in the specification, these phrases are rejected under 35 USC 112, first paragraph, as being NEW MATTER.

Claims Rejected Under 35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1631

Claims 1-4 and 15-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

Claim 1 recites the phrase “to make genotype calls” which lacks clarity. It is unclear on what the computer system is making these calls. Clarification of the metes and bounds of this phrase via clearer claim wording is requested. Claims 2-4 and 15-27 are also rejected due to their direct or indirect dependency from claim 1.

Claim 15 recites the phrase “one day” which is vague and indefinite. It is unclear how Applicants intend to use the term “day” as some laboratory work a standard 8-hour days, part-time workers might work 4-hour days, and workaholic workers might work more than 16 hours a day. Clarification of the metes and bounds of this phrase, via clearer claim wording is requested.

Claims 18-20 and 22 are vague and indefinite due to the unclarity of citing an abbreviation, such as “PCR” and “kb”. Correction is suggested by amending in of the full name in parentheses.

Claim 4 recites the phrase “the method step” which lacks proper antecedent basis. Claim 1, from which claim 4 depends, does not contain method steps so it is unclear to what the method step is referring. Correction of the antecedent basis for this phrase is requested.

Claim 4 recites the phrase “analyzing the hybridization” which lacks proper antecedent basis. Claim 1, from which claim 4 depends, does mention hybridization data (lines 7 and 8), but not the act of hybridization itself. Correction of the antecedent basis for this phrase is requested.

Claim 4 recites the phrase “the genotype” which lacks proper antecedent basis. Claim 1, from which claim 4 depends, does mention plural genotypes (line 1) and genotype calls (line 8),

Art Unit: 1631

but not the singular genotype as stated in claim 4. Correction of the antecedent basis for this phrase is requested.

Claim 21 recites the phrase “feature sizes” which is vague and indefinite. It is unclear what is meant by this phrase. For example, the feature sizes may include the size of the actual array or the size of a particular feature within the array. Clarification of the metes and bounds of the claim via clearer claim wording is requested. Claims 22-25 are also rejected due to their dependency from claim 21.

Claim Rejections – 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 17-18, 20, and 26 are rejected under 35 U.S.C. 102(a) and 35 U.S.C.

102(e)(1) as being anticipated by Bass et al. (2001/0039014 A1).

Bass et al. disclose automated devices and systems for arraying nucleic acids and for making and copying arrays, for performing in vitro translation and/or transcription of nucleic acid libraries, and for screening (abstract and paragraph 0002). Bass et al. disclose automated

Art Unit: 1631

systems to assess biological phenomena including gene expression levels in response to stimuli (high throughput DNA genotyping), as well as integrated systems for performing mixing experiments (sample preparation method), DNA amplification (PCR), and DNA sequencing (genotyping) (paragraph 0003). Figure 13 shows a DNA fragment preparation device (paragraph 0111). Bass et al. disclose laboratory attempts to meet increased demand for product development and research with minimal use of laboratory personnel (paragraph 0003). Bass et al. disclose using a nucleic acid shuffling module to dispense elongated nucleic acids into one or more multiwell plates (paragraph 0019) which represents an automated high density probe array loader, as stated in instant claim 1. Bass et al. disclose automated systems with robotics and fluid handling modules such as for microtiter tray manipulation (paragraph 0006) which is reasonably interpreted to be a sample preparation automation system, as stated in instant claims 1 and 2. Bass et al. disclose using devices and systems using an array of reaction mixtures that include one or more diversified nucleic acids (i.e. mutagenized or transcribed mutagenized) (paragraph 0010) which represent variation detection (an automated high density probe array loader), as stated in instant claim 1. Bass et al. disclose libraries that involve hybridization to a selected nucleic acid probe (paragraph 0195). Bass et al. disclose using PCR with techniques for rapid genotyping and quantification with hybridization probes (paragraph 0332). Bass et al. disclose using two probes labeled with different fluorophores that transfer energy between them to become excited and detected if a desired genotype is present (paragraphs 0335 and 0336). Bass et al. disclose the devices and integrated systems contain a bar-code sample tracking module which includes a bar code reader and a computer readable database (memory) with bar codes for corresponding arrays (paragraph 0011), as stated in instant claims 1, 3, 17, and 26.

Art Unit: 1631

Bass et al. disclose data obtained by the detection device is processed, stored, and analyzed by a computer system including a microprocessor and memory (paragraph 0423). Bass et al. disclose using PCR to amplify elongated nucleic acids to produce an amplified array of elongated nucleic acids (paragraph 0019) which represents long range PCR amplification, as stated in instant claim 18. Bass et al. disclose various sources of nucleic acids, including cDNA, DNA generated by reverse transcription, and antisense nucleic acid (paragraph 0020), as stated in instant claim 20. Bass et al. disclose simultaneous addition, cleaving and synthesizing of one or more DNA and antisense nucleic acid (paragraphs 0019 and 0070). Bass et al. disclose using nucleic acid fragments up to about 100 bases (paragraph 0238). Bass et al. disclose a nucleic acid shuffling or mutagenesis module which is preceded by a module which allows overlapping of oligonucleotides to be assembled into multimers (paragraph 0014), which represents tiling. Bass et al. disclose selecting, recombining, and re-arraying one or more members (nucleic acid) of an array (paragraph 0082) which represents a contiguous sequence being tiled on an array. Bass et al. disclose the analysis device allows one to quantitatively measure the frequency of recombination between DNA polymorphisms in parental genes (paragraph 0554).

Thus, Bass et al. anticipate the limitations in claims 1-4, 17-18, 20, and 26.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located

Art Unit: 1631

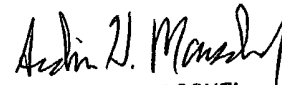
in Crystal Mall 1. The faxing of such papers must conform to the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (571) 272-0549.

March 1, 2004


ARDIN H. MARSCHEL
PRIMARY EXAMINER